

Page 22 Table 1.5.3

Replace with:

Table 1.5: 1 Hazard Ratios and CIs for Primary Endpoint - Stroke/SEE

	DE 110 BID vs Warfarin	DE 150 BID vs Warfarin
Hazard ratio (SE)	0.90 (0.09)	0.65 (0.07)
95% CI	0.74, 1.10	0.52, 0.81
97.5% CI	0.71, 1.13	0.51, 0.83
P-value for non-inferiority using 1.46	<0.0001	<0.0001
P-value for non-inferiority using 1.38	<0.0001	<0.0001
P-value for superiority	0.2943	0.0001

Source: NDA Amendment; Table 15.2.1.1: 3, Table 15.2.1.1: 4, Table 15.3.5.4: 4

Page 25, third paragraph, second sentence, starting “However, when looking...”

Replace with:

DE 110 BID had bleeding rates comparable to well-controlled warfarin (TTR \geq 65% or 68%) with hazard ratios near 1.00. DE 150 BID bleeding rates were slightly higher than well-controlled warfarin. For TTR \geq 68%, bleed rates on warfarin were significantly lower than DE 150 BID.

Page 72, third paragraph, the wrong numbers are stated for disposition

In the text it should be 17,360 (96.2%) from 17,321(96.0%)

Page 102 section 7.1 first paragraph

Replace with:

DE 110 BID bleeding rates were lower than warfarin for the categories major bleeds, life-threatening bleeds, intracranial hemorrhages, hemorrhagic stroke and any bleeds, with all confidence intervals excluding 1.00 for the comparison against warfarin. DE 150 BID had fewer bleeds than warfarin for major bleeds, life-threatening bleeds, intracranial hemorrhages, hemorrhagic strokes, and any bleeds, with the 95% confidence interval for comparison with warfarin excluding 1.00 for all these categories except major bleeds. Comparing the two doses of dabigatran, DE 110 BID was associated with less bleeding than DE 150 BID for all the categories above, with the 95% CI excluding 1.00 for major bleeds and any bleeds

On page 121, last sentence in the paragraph (starting “DE 150 BID compared to well controlled...”

replace with:

DE 110 BID bleeding rates were lower than warfarin for the categories major bleeds, life-threatening bleeds, intracranial hemorrhages, hemorrhagic stroke and any bleeds, with all confidence intervals excluding 1.00 for the comparison against warfarin. DE 150 BID had fewer bleeds than warfarin for major bleeds, life-threatening bleeds, intracranial hemorrhages, hemorrhagic strokes, and any bleeds, with the 95% confidence interval for comparison with warfarin excluding 1.00 for all these categories except major bleeds. Comparing the two doses of dabigatran, DE 110 BID was associated with less bleeding than DE 150 BID for all the categories above, with the 95% CI excluding 1.00 for major bleeds and any bleeds